

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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GEORGE LEHMANN and INSURED	:
BENEFIT PLANS, INC., Individually and on	:
Behalf of All Others Similarly Situated,	:
Lead Plaintiffs,	:
-against-	:
OHR PHARMACEUTICAL INC., JASON	:
SLAKTER, SAM BACKENROTH, and	:
IRACH TARAPOREWALA,	:
Defendants.	:
-----	X

INDEX NO. No. 1:18-cv-01284-LAP

Judge Loretta A. Preska

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS
THE AMENDED CLASS ACTION COMPLAINT

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Defendants Ohr Pharmaceutical Inc. (“Ohr” or the “Company”), Jason Slakter, Sam Backenroth, and Irach Taraporewala (the “Individual Defendants,” and together with Ohr, “Defendants”) respectfully submit this memorandum of law in support of their Motion to Dismiss the Amended Class Action Complaint, Dkt. No. 44 (the “Complaint”).

PRELIMINARY STATEMENT

Investments in biotechnology companies like Ohr that are engaged in clinical trials are, by definition, risky and speculative. Ohr said as much in its public disclosures. While rightfully optimistic, Ohr’s disclosures were transparent and warned of the risks of failure of the clinical trials of its lead drug candidate, Squalamine. Section 10(b) of the Exchange Act does not protect investors who invest in scientific endeavors which, despite being encouraged by experts and closely-regulated by rigorous FDA procedure, nevertheless fail. Many drugs that appear promising in early phase clinical trials and even receive fast-track designation by the FDA fail to ultimately prove effective in later clinical trials. That is what happened here and nothing more.

Among the glaring deficiencies, the Complaint does not account for: (i) the public nature of all information related to clinical trials of Squalamine (or Lucentis) dating back to 2006; (ii) Ohr’s reformulation of Squalamine to be used as a daily administered eye drop for use in combination with Lucentis (compared to Genaera’s intravenous, single agent formulation); and (iii) Ohr’s exhaustive risk disclosures related to its clinical trials and the possibility that its lead drug candidate would fail – the very risk that unfortunately materialized and on which Plaintiffs base their claims. Most significantly, the Complaint lacks well-pleaded allegations of falsity. Plaintiffs do not allege that Defendants misrepresented the methodology used for any of the Squalamine clinical trials or misstated the results of those trials. Instead, Plaintiffs merely allege that Defendants described the results too optimistically, and do not support even these weak

contentions with a single confidential witness or internal document. Rather, Plaintiffs rely solely on hindsight and their own unsourced opinions, scientifically flawed interpretations, and rank speculation to state their perspective on how Ohr should have conducted its business. Critically, Plaintiffs ignore Ohr's detailed disclosures as well as the internal contradictions in their own Complaint and supporting documents that make clear Defendants' statements are not indicative of fraud but, rather, are legally-protected differences of opinion.

The Complaint likewise fails to allege a strong inference of scienter. Plaintiffs have neither adequately alleged that Defendants had the motive and opportunity to engage in fraud – *indeed, none of the Defendants are alleged to have sold stock during the lengthy 4-year putative class period* – nor acted consciously or recklessly by ignoring known information that was inconsistent with their public statements. The Complaint also does not allege loss causation, as the “corrective disclosure” – the Company's announcement that the MAKO Trial had been unsuccessful – necessarily could not have revealed anything new about the results of the prior IMPACT Trial. Finally, Plaintiffs' claims are barred by the statute of limitations.

For each of these reasons, this Court should dismiss Plaintiffs' claims with prejudice.

STATEMENT OF FACTS

A. Allegations of the Amended Complaint.

The Complaint spends considerable time on (i) the background and age of Ohr's CEO/COO (Am. Compl. ¶¶ 4, 42, 130); (ii) Ohr's origins and corporate structure (*id.* at ¶¶ 2, 28-30); (iii) conduct about Ohr's founders (not named as Defendants in this action), which Plaintiffs acknowledge is “not related to Ohr” (*id.* at ¶¶ 28, 30); and (iv) a chronology, table of contents, and glossary of characters.¹ But these allegations do nothing to advance the substance of

¹ The conclusory allegations of the Complaint are assumed to be true solely for the purposes of this Motion. In addition to Plaintiffs' allegations, the Court may properly take judicial notice of

Plaintiffs' claims, instead serving as a thinly-veiled attempt to bias the Court and paint Defendants in a negative light.² When stripped of these senseless digressions, what is left are Plaintiffs' speculative *opinions* that (1) Ohr purchased a drug whose previous owner had halted and discontinued clinical trials, and (2) the control group in Ohr's Phase 2 trials in 2015 fell below a hypothetical "average" norm. (*See* Am. Compl. at ¶¶ 77-81, 82-92 & 93-112.) Each premise is fatally flawed.

B. Ohr Had Good Reason to Purchase Squalamine and Proceed with Development.

1. Background of Squalamine Clinical Trials and Leading Experts' Support of Continued Development.

Genaera Corporation was a company founded in 1987 as Magainin Pharmaceuticals. One of its original development programs was Squalamine. (*Id.* at ¶¶ 2, 38.) When Genaera

all public documents annexed to the Affirmation of Aurora Cassirer in Support of Defendants' Motion to Dismiss, filed contemporaneously herewith ("Cassirer Affirm."). *See Pehlivanian v. China Gerui Advanced Materials Grp., Ltd.*, No. 14 Civ. 9443, 2017 WL 1192888, at *6 (S.D.N.Y. Mar. 29, 2017) (on a motion to dismiss, "the Court may consider documents that are referenced in the complaint, documents that the plaintiffs relied on in bringing suit and that are either in the plaintiffs' possession or that the plaintiffs knew of when bringing suit, or matters of which judicial notice may be taken."); *Staehr v. Hartford Fin. Servs. Grp.*, 547 F.3d 406, 424 (2d Cir. 2008) (affirming judicial notice of "media reports, state court complaints, and regulatory filings"); *In re MBIA, Inc. Sec. Litig.*, 700 F. Supp. 2d 566, 576 (S.D.N.Y. 2010) (taking judicial notice of SEC disclosures, news publications, and analyst reports).

² The information *publicly available* at the time Plaintiffs invested between April 8, 2014 and January 4, 2018 (Dkt. No. 15-2) disclosed the credentials of Irach Taraporewala – a veteran healthcare executive with lengthy experience in drug development and regulatory strategy – and Sam Backenroth – a 26-year-old who graduated from Tuoro College with a bachelor's degree in finance and experience in financing biotechnology companies. Ohr Pharm., Inc.'s Form 8-K, Ex. 99.1 Press Release (Apr. 12, 2010), annexed as Ex. 1 to Cassirer Affirm. Ohr also disclosed it was not first established as a pharmaceutical company and was entering the industry to do a "a rollup of undervalued biotechnology companies and assets." Ohr Pharm., Inc.'s Annual Report (Form 10-K), (Jan. 13, 2012), annexed as Ex. 2 to Cassirer Affirm.; Ohr Pharm., Inc.'s Annual Report (Form 10-K/A) (Jan. 19, 2010), annexed as Ex. 3 to Cassirer Affirm. Plaintiffs cannot now complain of facts widely available at the time.

tested Squalamine, it found that it was a potent anti-angiogenic³ which opened up its potential use in diseases where angiogenesis played a role, including wet-AMD. Genaera aimed its research at wet-AMD, which causes blindness in millions of elderly individuals. Genaera's data demonstrated that Squalamine was active *in vitro*, in multiple in-vivo disease models and in clinical trials as a single stand-alone drug ("monotherapy") for wet-AMD.⁴

The release of data from Lucentis announced in July 2005 (MARINA study) and in 2006 demonstrated results that were better than those seen with Squalamine alone, but that does not mean that Squalamine did not demonstrate activity in an FDA-approvable endpoint.⁵ Genaera's

³ C. Gentili et al., *Squalamine, An Anti-Angiogenic Factor, Alters Endochondral Ossification & Long Bone Formation*, Orthopedic Research Society (Feb. 2001), annexed as Ex. 4 to Cassirer Affirm.

⁴ Genaera's first clinical trial, Study 106, was the first study conducted with Squalamine as a monotherapy using an IV formulation. The results demonstrated that patients were showing vision improvement and stabilization when dosed weekly. Genaera Corp.'s Form 8-K, Ex. 99.2 (Oct. 7, 2003), annexed as Ex. 5 to Cassirer Affirm.; Genaera Corp.'s Form 8-K, Ex. 99.1 Press Release (Oct. 7, 2003), annexed as Ex. 6 to Cassirer Affirm. Based on these results, three Phase II studies were initiated. Genaera Corp.'s Form 8-K, Ex. 99.1 Press Release (Apr. 22, 2004), annexed as Ex. 7 to Cassirer Affirm. One of those trials, Study 207, was performed to better understand the drug and to establish possible correlations between toxicity/efficacy parameters and drug concentrations. The data demonstrated that "***all subjects receiving the 40 mg dose had preserved or improved vision***" during evaluation in both affected eyes through month 4 after weekly therapy." Genaera Corp.'s Form 8-K, Ex. 99.1 Press Release (May 2, 2005) (emphasis added), annexed as Ex. 8 to Cassirer Affirm. It also demonstrated an effect in "both affected eyes in ***all patients with 40 mg of EVIZON regardless of the stage of the lesion***" (late stage lesions were termed "fellow eye"), which suggested a differentiated mechanism of action. Genaera Corp.'s Form 8-K, Ex. 99.1 Press Release (Feb. 25, 2005) (emphasis added), annexed as Ex. 9 to Cassirer Affirm. Study 209 demonstrated that 83% of patients in the highest dose (40mg) achieved vision stabilization or improvement at week 24 (losing less than 15 letters of vision), which is the same parameter on which the FDA approved Macugen, Visudyne, and Lucentis. See Genaera Corp.'s Form 8-K, Ex. 99.1 Press Release (Mar. 1, 2006), annexed as Ex. 10 to Cassirer Affirm.

⁵ Lucentis, Visudyne, and Macugen were all approved by the FDA based on the proportion of patients maintaining vision (as defined by losing less than 3 lines of vision). See FDA label for LUCENTIS®, annexed as Ex. 11 to Cassirer Affirm. The Squalamine phase 2 results in this endpoint were higher than that achieved with Visudyne and Macugen, the two FDA approved treatments for wet-AMD at the time. See FDA label for VISUDYNE®, annexed as Ex. 12 to Cassirer Affirm.; FDA label for MACUGEN®, annexed as Ex. 13 to Cassirer Affirm.

efforts to improve vision to be competitive with Lucentis continued even while the ongoing Squalamine studies foundered for lack of patient enrollment and were ultimately discontinued.⁶ Nevertheless, leading experts in the field, including Dr. Thomas Ciulla – recognizing the reason Genaera discontinued the Squalamine program as being commercial in nature⁷ – concluded, after Genaera’s trial and program termination, that further clinical studies of Squalamine should be pursued as a combination therapy in wet-AMD:

*Although effective as monotherapy, it is unlikely that squalamine will be more effective than either bevacizumab (Avastin®) or ranibizumab (Lucentis®). However, it is possible that Squalamine, unlike other agents in this category, may be used in combination with other treatment modalities in clinical practice. It may have an especially useful role as a component of combination therapies, since it is administered systemically and involves a mechanism not dependent on direct VEGF binding, thus complementing the currently standard intravitreal injections of agents that directly bind and inhibit existing intravitreal VEGF. Further clinical studies with squalamine and other antiangiogenics, in combination with PDT, or with other local therapies are necessary to determine the nature, timing and most appropriate subject based for such regimens.*⁸

⁶ Genaera Corp.’s Form 8-K, Ex. 99.1 Press Release (Mar. 1, 2006), annexed as Ex. 14 to Cassirer Affirm.

⁷ Plaintiffs claim Ohr’s statements about beneficial effects observed by Genaera’s clinical trials were misleading because Genaera terminated its development of Squalamine for the treatment of wet-AMD based on its trial data. (See, e.g., Am. Compl. ¶ 77.) Not so. Genaera terminated its clinical trials not for lack of efficacy but because “[s]ignificant changes took place in the market for AMD treatments in 2005,” including FDA approval of Lucentis. Ex. 14. Moreover, Plaintiffs’ claims are belied by Genaera’s own SEC filings characterizing its Phase II clinical trial preliminary results as “positive” and “encourag[ing].” Genaera Corp.’s Form 8-K, Ex. 99.1 Press Release (Oct. 19, 2005), annexed as Ex. 15 to Cassirer Affirm. According to Genaera, its EVIZON (Genaera’s trade name for its Squalamine formulation) phase 2 clinical trials indicated “intravenous EVIZON **consistently stabilizes or improves vision** in both eyes in a dose responsive fashion” and showed “**marked improvement of visual acuity in the fellow affected eyes of subjects with poorer vision.**” Genaera Corp.’s Form 8-K, Ex. 99.1 Press Release (Apr. 26, 2006) (emphasis added), annexed as Ex. 16 to Cassirer Affirm.

⁸ Thomas Ciulla et al., *Squalamine lactate for the treatment of age-related macular degeneration*, 2 EXPERT REV. OF OPHTHALMOL. 165 (2007), annexed as Ex. 17 to Cassirer Affirm. Notably, Plaintiffs expressly mention Thomas Ciulla in their Complaint as a prior investigator of Genaera’s phase II trials and cite articles related to his participation in those trials. (Am. Compl. ¶ 116.) Any implication that Dr. Ciulla had any information inconsistent with Defendants’ conclusions and public statements, is not borne out either in the Complaint or in the publications.

2. Ohr's Strategy to Overcome Delivery, Dosing, and Commercial Deficiencies.

Based on pre-clinical and clinical evidence, Ohr understood Squalamine was an active molecule with potential to treat patients with wet-AMD if delivery and dosing deficiencies could be overcome.⁹ Ohr addressed the dosing deficiency by proposing a topical daily administration route as a way to maintain therapeutic level concentrations as compared to Genaera's intravenous formulation.¹⁰ A less invasive topical administration possessed advantages over intravitreal injections and held out promise for a commercially viable path forward.¹¹

Ohr's proposed clinical development plan to evaluate Squalamine in clinical trials when used in combination with Lucentis to improve visual acuity was precisely the type of combination therapy recommended by the experts.¹² And to allege that, despite Genaera's development of Squalamine in a different formulation, delivery, and therapy regimen, Ohr had reason to know the program would be unsuccessful in the MAKO Trial is absurd.

3. Plaintiffs' Control-Arm Argument Is Wrong and Reflects a Lack of Understanding of Science and Drug Development.

Plaintiffs' argument that Ohr should have known, based on other studies, that its control-arm results were flawed is based on a concept that is scientifically preposterous. Plaintiffs' failed attempt at creating an "appropriate control group" involves a comparison of historical Lucentis trials which are not comparable at all. In so doing, Plaintiffs not only ignore basic

⁹ *Id.*

¹⁰ The Genaera intravenous infusion ("IV") which was delivered infrequently (weekly and then monthly) likely did not last above the therapeutic threshold for more than a few days based on pharmacokinetic parameters; thus, resulting in inadequate dosage. There are multiple examples in the literature of molecules that traverse to posterior ocular tissues after topical administration. See Daniel F. Kiernan, M.D. & Jennifer I. Lim, M.D., *Topical Drug Delivery for Posterior Segment Disease*, RETINA TODAY (May/June 2010), annexed as Ex. 18 to Cassirer Affirm.

¹¹ See Ohr Pharm., Inc.'s Quarterly Report (Form 10-Q) (May 11, 2012), annexed as Ex. 19 to Cassirer Affirm.

¹² Patrizia Buchholz, PhD et al., *Combination Therapies for Wet AMD: Latest Developments*, RETINAL PHYSICIAN (Mar. 1, 2010), annexed as Ex. 20 to Cassirer Affirm.

scientific and FDA guidelines, but also show a fundamental lack of understanding of drug development. Historical controls are a poor secondary method to determine the effect of a treatment compared to a randomized, double-masked, multi-center clinical trial like the IMPACT study, as evidenced by the FDA and other regulatory authorities mandating such controlled studies for drug approval except in very rare circumstances such as ultra-rare diseases where external (historical) controls may be allowed.¹³ Moreover, a historical control could only be useful in gaining some perspective of trial results if all parameters were matched between the study and the historical control, including, but not limited to: type of study (randomized vs. non-randomized, masked vs. unmasked, prospective vs. retrospective); study size; demographics (age, sex, race); lesion type and size; visual acuity; central retinal thickness; treatment naïve or previously treated; treatment regimen (monthly, PRN, treat and extend, etc.); drug (Lucentis vs. Avastin); visit schedule; timing of endpoints; location; and year study was conducted. No study cited in Plaintiffs’ “analysis” suffices.

The IMPACT Trial was a randomized, double-masked, prospective trial enrolling treatment naïve patients based on specific parameters defined in the protocol. Unlike all other trials in Plaintiffs’ table, with the exception of the CATT study, the IMPACT Trial had patients

¹³ Highlighting this point and adding much-needed perspective to Plaintiffs’ specious argument regarding Lucentis, is clear FDA guidance that historically controlled studies should be reserved only for special circumstances. *See* U.S. DEP’T OF HEALTH & HUMAN SERVS. FOOD & DRUG ADMIN.’S GUIDANCE FOR INDUSTRY: E 10 CHOICE OF CONTROL GRP. & RELATED ISSUES IN CLINICAL TRIALS (May 2001) (noting that “[e]xternal (historical) control groups, regardless of the comparator treatment,” carry “serious concerns about the ability of such trials to ensure comparability of test and control groups and their ability to minimize important biases, making this design usable *only in unusual circumstances*”) (emphasis added), annexed as Ex. 21 to Cassirer Affirm.; *see also id.* at 26-27. Thus, the focus on only the historical data and the attempt to incorporate all historical clinical trial data from Lucentis studies – despite, and without any regard for numerous critical parameters, including highly variable methodology, treatment approach, dosage, and length of trial – is inconsistent with governing FDA guidelines.

receiving a single initial injection of Lucentis followed by “pro re nata” (PRN) – *i.e.*, dosed as needed, not on a regimented routine – Lucentis with a 9-month endpoint.

The table below is copied from Paragraph 55 of the Complaint and further analyzed for scientific relevance based on the scientific norms outlined above, with the IMPACT Trial data added to the top of the chart to provide appropriate context:

Study Name	Date of Publication	BCVA Improvement With Injections As Needed Per Set Protocol	BCVA Improvement With Monthly Injections	
IMPACT (Lucentis control arm)	2015	5.7 Letters 26% ≥3 Line Vision Gains	N/A	
		PRN studies using 3 loading doses not comparable to IMPACT and CATT single injection PRN regimen	Monthly regimen data not applicable to PRN regimens and data	
Study Name	Date of Publication	BCVA Improvement With Injections As Needed Per Set Protocol	BCVA Improvement With Monthly Injections	Comments
MARINA	2006	N/A	7.2 letters at 9 mos. 7.2 letters at 12 mos. 6.6 letters at 24 mos.	Monthly not comparable to PRN regimen.
ANCHOR	2006	N/A	11.4 letters at 9 mos. 11.3 letters at 12 mos.	Monthly not comparable to PRN regimen.
PrONTO	2007	9.3 letters at 12 mos. 11.1 letters at 24 mos.	N/A	Small, uncontrolled, single center study.
A Treat and Extend Regimen Using Ranibizumab for Wet AMD: Clinical and Economic Impact	2010	9.7 letters at 24 mos.	N/A	Small, retrospective, uncontrolled, single center study using monthly until dry and then T&E not PRN. The cited paper does not include mean visual acuity gains.
Inject and Extend Dosing Versus Dosing as Needed	2011	2.3 letters at 12 mos. as needed 10.8 letters at 12 mos. inject & extend	N/A	Small, retrospective, uncontrolled, single center study. T&E is not comparable to PRN as evidenced by these results.
CATT	2011	7.2 letters at 9 mos. 6.8 letters at 12 mos. 6.7 letters at 24 mos.	7.5 letters at 9 mos. 8.5 letters at 12 mos. 8.8 letters at 24 mos.	
VIEW1	2012	N/A	8.1 letters at 12 mos.	Monthly not comparable to PRN regimen.
VIEW2	2012	N/A	9.4 letters at 12 mos.	Monthly not comparable to PRN regimen.
FUSION	2012	5.6 letters at 12 mos.	N/A	Small, uncontrolled, single center study using combination of PRN & fixed dosing.
HARBOR	2013	8.2 letters at 12 mos. 7.9 letters at 24 mos.	10.1 letters in at 12 mos. 9.1 letters at 24 mos.	
VIEW 96 Week Results	2013	7.9 letters at 22 mos	N/A	Monthly treatment used for first year and then modified PRN. Not comparable.
IVAN	2013	7.2 letters at 12 mos. ¹³ 4.9 letters at 24 mos.		Incorrect. Results combined drugs, not regimens. PRN +5.0 letters at month 12.
LUCAS	2013	8.2 letters at 12 mos.	N/A	T&E not comparable to PRN regimen.
GEFAL	2013	3.63 letters at 12 mos.	N/A	Incorrect. PRN +2.9 letters at month 12.
MANTA	2013	4.1 letters at 12 mos.	N/A	
Reducing the clinical burden of ranibizumab treatment for neovascular age-related macular degeneration using an individually planned regimen	Apr. 2014	9.8 letters at 12 mos.	N/A	Small, single center study that used a personalized treatment algorithm to achieve better results than PRN or T&E. Not comparable.
BRAMD	Apr. 2014	N/A	6.4 letters at 12 mos.	Monthly not comparable to PRN regimen.
Average for all trials:		7.94 letters		

The above analysis demonstrates that the studies in Plaintiffs' chart, with the exception of the CATT study, should be excluded from this attempt to retroactively determine an "appropriate control group" standard by virtue of the fact that they are not even remotely comparable.

- All studies without PRN Lucentis dosing are inappropriate comparators. Monthly Lucentis produces very different visual and anatomical differences versus PRN.¹⁴
- The table includes very small, uncontrolled and nonrandomized studies, single center trials and retrospective case studies. These are wholly inappropriate comparators versus a randomized, double-masked, multi-center, controlled study like IMPACT.
- Plaintiffs indiscriminately include multiple data points from some studies but not others and incorporate all of the endpoints into the "average" with no supporting rationale.
- Monthly treatment regimens are combined with PRN and treat and extend regimens.
- Multiple data points in the table are incorrect and conflict with the cited papers.
- Twelve-month data endpoints cannot be compared with a 9-month endpoint.
- All of the PRN studies, with the exception of the CATT study, used a mandatory 3-dose Lucentis loading regimen which changes visual outcomes at final analysis.¹⁵

¹⁴ Christine M. Shmucker et al., *Treatment as Required versus Regular Monthly Treatment in the Management of Neovascular Age-Related Macular Degeneration: A Systematic Review and Meta-Analysis*, PLOS ONE (Sept. 14, 2015), annexed as Ex. 22 to Cassirer Affirm.

¹⁵ See Geeta A. Lalwani, M.D., *All About PrONTO: Study Yielded Good Results in AMD With Treatment Guided by OCT*, RETINA TODAY (May 2007), annexed as Ex. 23 to Cassirer Affirm.; Lalwani GA, *A Variable-dosing Regimen with Intravitreal Ranibizumab for Neovascular Age-related Macular Degeneration: Year 2 of the PrONTO Study*, 148 AM. J. OPHTHALMOL. 43 (July 2009), annexed as Ex. 24 to Cassirer Affirm.; Allen C. Ho, MD et al., *Twenty-four-Month Efficacy and Safety of 0.5 mg or 2.0 mg Ranibizumab in Patients with Subfoveal Neovascular Age-Related Macular Degeneration*, 121 OPHTHALMOL. 2181 (Nov. 2014), annexed as Ex. 25 to Cassirer Affirm.; Usha Chakavarthy et al., *Ranibizumab versus Bevacizumab to Treat Neovascular Age-related Macular Degeneration: One-Year Findings from the IVAN Randomized Trial*, 119 OPHTHALMOL. 1399 (July 2012), annexed as Ex. 26 to Cassirer Affirm.; Laurent Kodjikian et al., *Ranibizumab versus Bevacizumab for Neovascular Age-related Macular Degeneration: Results from the GEFAL Noninferiority Randomized Trial*, 120 OPHTHALMOL. 2300 (Nov. 2013), annexed as Ex. 27 to Cassirer Affirm.; G.J. Jaffe, MD et al., *Macular Morphology and Visual Acuity in the Comparison of Age-related Macular*

- The data is not presented in ways that can be interpreted. For example, the IVAN study combines PRN treatment of Avastin and Lucentis.¹⁶ Multiple studies have shown that Avastin performs differently than Lucentis.¹⁷ Also of note is the inaccurate notation by Plaintiffs regarding data in the IVAN study.
- The number of participants in the studies are vastly different or not comparable. Some of the studies have less than 100 subjects and others include more than 1,000.
- There is significant variability on what the control arm is “supposed to look like,” especially in PRN studies.¹⁸ The IMPACT study falls comfortably within the range of PRN results. By taking an average of a “fruit basket” instead of an apples-to-apples comparison, the only conclusion is that there are several studies that overperformed this “fruit basket” average and several that underperformed.
- Significant differences exist in the protocols and enrolled populations that would affect outcomes,¹⁹ including, but not limited to: lesion type and size; baseline visual acuity; central retinal thickness; demographics; location; year study was conducted; and treatment naïve or previously treated.
- The analysis fails to account for the totality of vision outcomes including mean VA, 3-line gains, 20/40 functional vision, and final visual acuity.
- Plaintiffs’ analysis omits the PIER study that is on the FDA label for Lucentis,^{20,21} and in which subjects *lost* an average of 0.9 letters at 12 months.

There simply is no scientifically-sound basis for Plaintiffs’ attempt to compile all data available for a myriad of incomparable clinical trials or to recalibrate Defendants’ sound judgment calls and legally-protected interpretations regarding the IMPACT Trial data.

Degeneration Treatments Trials, 120 OPTHALMOL. 1860 (Sept. 2013), annexed as Ex. 28 to Cassirer Affirm.

¹⁶ See Ex. 26.

¹⁷ Ex. 22; *see also* Ex. 25, 26, and 28.

¹⁸ See Ex. 23, 25, 26, 27, and 28.

¹⁹ X. Zhang et al., *Baseline Predictors of Visual Acuity Outcome in Patients with Wet Age-Related Macular Degeneration*, BIOMED RESEARCH INT’L (Feb. 26, 2018), annexed as Ex. 29 to Cassirer Affirm.

²⁰ See Ex. 11. The PIER study is identified as study AMD-3.

²¹ C.D. Regillo et al., *Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1*, 145 AM. J. OPTHALMOL. 239 (Feb. 2008), annexed as Ex. 30 to Cassirer Affirm.

ARGUMENT

POINT I.

**PLAINTIFFS FAIL TO PLEAD A VIOLATION OF SECTION 10(B)
AND RULE 10B-5 WITH THE REQUISITE PARTICULARITY**

To survive a motion under Federal Rule of Civil Procedure 12(b)(6), a complaint must “contain sufficient factual matter . . . to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plausibility is present “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Dismissal is appropriate where the plaintiff fails “to raise a right to relief above the speculative level.” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

To state a securities fraud claim under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, a plaintiff must adequately plead: (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 460-61 (2013); *ATSI Commc’ns, Inc.*, 493 F.3d at 101. “[F]ailure to establish any element is fatal.” *Leemon v. Burns*, 175 F. Supp. 2d 551, 557 (S.D.N.Y. 2001).

Plaintiffs’ claim under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), is subject to the heightened pleading requirements of the PSLRA, 15 U.S.C. § 78u-4, and Federal Rule of Civil Procedure 9(b). *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 168 (2d Cir. 2005). The PSLRA mandates that “securities fraud complaints ‘specify’ each misleading statement; that they set forth the facts ‘on which [a] belief’ that a statement is misleading was ‘formed;’ and that they ‘state with particularity facts giving rise to a strong inference that the defendant acted with the

required state of mind.” *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 81-82 (2006) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005)); 15 U.S.C. §§ 78u-4(b)(1)-(2). Similarly, Rule 9(b) requires Plaintiffs to “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004). Under these exacting standards, Plaintiffs do not “enjoy a ‘license to base claims of fraud on speculation and conclusory allegations.’” *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 813 (2d Cir. 1996).

The Complaint should be dismissed with prejudice as it does not state a violation of Section 10(b) or Rule 106-5 because it does not adequately allege (a) a materially false or misleading statement, (b) scienter, or (c) loss causation.

A. The Complaint Fails to Plead a Material Misstatement or Omission.

Plaintiffs’ prolix Complaint challenges Defendants’ public statements regarding Genaera’s Phase II clinical trials, Ohr’s IMPACT Trial’s Interim Results, and the IMPACT Trial’s Topline results. (See Am. Compl. ¶¶ 10-17, 77-81, 82-92 & 93-112.) Many statements are forward-looking and non-actionable, while others are simply accurate statements that Plaintiffs deliberately skew in order to improperly poke holes in Ohr’s interpretation of its clinical trial results – something that, under the law, they simply cannot do. Nowhere in the Complaint are any factual allegations that Defendants knew their statements were false at the time they were made. Rather, Plaintiffs allege only that leading scientists in the field – including Dr. Jeffrey S. Heier and Dr. David S. Brown who sit on Ohr’s Scientific Advisory Board – had experience with Lucentis and, thus, “undoubtedly explained their knowledge” to Defendants such that they “would have known” about the Lucentis trials. (See *id.* at ¶¶ 120, 122-23.) But alleging prior knowledge of Lucentis alone misses the mark, because what Plaintiffs’ fail to

consider is that these same leading scientists – like Defendants – believed in the efficacy of Squalamine. In fact, there was a consensus among leading scientists that Squalamine, a topical therapeutic, was a promising new drug in this industry.²²

“Federal securities law ‘does not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading.’” *Calfo v. Messina*, No. 15 Civ. 4010 (LGS), 2016 WL 3661548, at *6 (S.D.N.Y. July 5, 2016) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011)). “A violation of Section 10(b) and Rule 10b-5 premised on misstatements cannot occur unless an alleged material misstatement was false at the time it was made.” *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), *aff’d* by 604 F. App’x 62 (2d Cir. 2015). To that end, “[p]ublic statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest research standards, provided that [the] findings and methods are described accurately.” *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711 (PKC), 2013 WL 2399869, at *6 (S.D.N.Y. May 29, 2013) (citing *Kleinman v. Elan Corp.*, 706 F.3d 145, 153-55 (2d Cir. 2013)). Instead, where a defendant pharmaceutical company has

²² See Ohr Pharm., Inc. Press Release (Mar. 29, 2016) (Dr. David S. Boyer stating that “Based on my clinical experience, Squalamine is a promising drug with the potential to non-invasively improve visual function over the current standard of care. I look forward to the opportunity to enroll patients in this important clinical study.”), annexed as Ex. 31 to Cassirer Affirm.; Ohr Pharm., Inc. Press Release (May 2, 2016) (Dr. David Brown stating “I am excited to be playing such a key role in this important Phase 3 clinical program . . . A topical medication with the potential to improve visual outcomes would be a tremendous advance in the treatment of patients with wet-AMD.”), annexed as Ex. 32 to Cassirer Affirm.; Ohr Pharm., Inc. Press Release (Apr. 29, 2014) (Dr. Jeffrey S. Heier stating that “I am pleased with the continued progress of this important study and look forward to the upcoming planned interim analysis.”), annexed as Ex. 33 to Cassirer Affirm.

accurately described a study's methods, even if only minimally, it does not have to disclose all potentially relevant information or findings. *See id.*

1. Data Interpretation Is a Matter of Opinion and, Thus, Disagreement with Management's Opinions Cannot Establish Falsity for Section 10(b) Purposes.

The entire gist of Plaintiffs' Complaint is that, if one disregards Ohr's assessment of its control data in the 2012 IMPACT Study and instead uses a wholly speculative and scientifically unreliable fictitious "average" result for Lucentis – a method for which it cites no support – then all of Ohr's conclusions regarding the efficacy of the IMPACT trial results as "clinically meaningful" are false. (*See* Am. Compl. ¶¶ 10, 12-13, 17, 56-58.)²³ As demonstrated, Plaintiffs have no basis for averaging the results of previous Lucentis trials to be used throughout the Complaint and, in fact, such averaging to create a fictitious "control data" would be a breach of good scientific practice and conflicts with FDA guidance. (*See* pp. 7-10, *infra.*) *See also In re MELA Scis., Inc. Sec. Litig.*, No. 10-8774, 2012 WL 4466604, at *12 (S.D.N.Y. Sept. 19, 2012) (a company has no duty to characterize accurately stated data in plaintiffs' preferred manner). Clearly, Ohr's disclosures regarding Squalamine in its IMPACT Trial, and in Genaera's previous Phase II clinical trials (*see* fn. 7, *infra.*), which together form the basis of Plaintiffs' fraud claims (Am. Compl. ¶¶ 82-112), are accurate and protected interpretations of the data.

This Court has been clear that a drug manufacturer's interpretation of clinical trial data is a statement of opinion that is "generally not actionable as fraud." *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528, 543-44 (S.D.N.Y. 2015), *aff'd sub nom Tongue v. Sanofi*, 816 F.3d 199 (2d

²³ Plaintiffs rely solely upon Dr. David Boyer's opinions of what a "clinically meaningful" or "clinically significant" overall improvement would be, and do not even provide that transcript for the Court. (Am. Compl. ¶¶ 10, 57.) Plaintiffs' sole reliance on the opinion of one scientist given on one telephone call cannot seriously serve as the sole basis of their claims. It also ignores the seminal fact that the IMPACT Trial resulted in a gain of 5.3 letters versus the Lucentis control arm (*id.* at ¶¶ 13, 68-69), which is undisputedly "clinically meaningful," even by Plaintiffs' standards (*id.* at ¶¶ 10, 57). As discussed herein, Plaintiffs' recalculation of the trial results is unfounded and not useful for purposes of analyzing Defendants' conclusions.

Cir. 2016). Indeed, courts have repeatedly found “‘publicly stated interpretations of the results of various clinical studies’ to be ‘opinions’ because ‘reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.’” *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 543; *In re MELA Scis., Inc. Sec. Litig.*, 2012 WL 4466604, at *13 (“Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial.”); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014). An opinion is only actionable in this context if “defendant’s opinions were both false and not honestly believed when they were made.” *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011); *see also In re Barclays Bank PLC Sec. Litig.*, No. 09 Civ. 1989, 2017 WL 4082305, at *10 (S.D.N.Y. Sept. 13, 2017).

In challenging Defendants’ disclosures, Plaintiffs entirely sidestep and fail to address that Defendants honestly believed that reformulating the drug based on the outcomes of prior trials would be successful – a fact which is fatal to Plaintiffs’ Section 10(b) claim. *See, e.g., Express Scripts Holding. Co. Sec. Litig.*, No. 16 Civ. 3338, 2018 WL 2324065, at *9 (S.D.N.Y. May 22, 2018) (“Even if Plaintiff had plausibly plead facts to show that [Defendant’s] accounting treatment should have been different, Plaintiff did not allege that Defendants ‘did not believe’ that the accounting treatment was appropriate during the Class Period.” (citing *City of Omaha, Neb. Civilian Emps.’ Ret. Sys. v. CBS Corp.*, 679 F.3d 64, 69 (2d Cir. 2012))). Because Plaintiffs do not (and cannot) allege that Defendants’ views were false or not honestly believed, Plaintiffs’ claim fails as a matter of law.

2. Plaintiffs’ Failure to Account for the Public Nature of the Clinical Trial Results for Lucentis Is Fatal to Their Claim.

In constructing the Complaint, Plaintiffs cobble together 17 supposed unique prior clinical trial results of Lucentis in wet-AMD patients that they claim shows “on average” that the

visual acuity results for the Lucentis Monotherapy Arm in the IMPACT Trial underperformed the historical results observed in prior studies of Lucentis. (Am. Compl. ¶¶ 55-56.) Critically, Plaintiffs cite just as many public articles and scientific publications which contain the data relied upon for Plaintiffs to craft the Complaint and chart of prior clinical trials upon which their claim in large part hinges. (*Id.* at ¶ 55 & n. 12.) Thus, the objective evidence is, and for many years prior to the class period has been, publicly available.

Still, Ohr's management made clear time and again that they relied upon the CATT Trial as most comparable to the Lucentis monotherapy control arm utilized in the IMPACT Trial:

When we first evaluated our Phase 2 data, one of the first things we have looked at was how closely our Lucentis mono-therapy control arm performed compared to prior study. As you recall the Lucentis PRN arm of the CATT trial, which was the large study comparing Lucentis to Avastin had a treatment regimen [and] inclusion criteria almost identical to that that we used in our study. And we saw that the outcome in our Lucentis monotherapy arm were very similar to the visual acuity outcomes seen in the comparable arm in the CATT study at months nine. This provided us with support to the improvements that we were seeing with Squalamine combination therapy in Phase 2 were real and replicable.

See Ohr Pharm., Inc., Q4 2016 Earnings Conference Call (Dec. 22, 2016) (presentation by Defendant Slakter), annexed as Ex. 34 to Cassirer Affirm. Plaintiffs' Complaint does nothing to refute this fact, focusing instead on Ohr management's alleged knowledge of prior Lucentis trials and ignoring their express opinion and determination based on scientific literature that the CATT Trial was the only reasonably appropriate comparable historical study to be used for perspective on the IMPACT Trial results. (*See* Am. Compl. ¶¶ 119-23.) Quite simply, there was a reasonable basis for Defendants' expressions of optimism, and the fact that the MAKO Trial was ultimately unsuccessful was a known risk. *See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1st Cir. 2008) ("[T]he investing public is well aware that drug trials are exactly that: trials to determine the safety and efficacy of experimental drugs.

And so trading in the shares of companies whose financial fortunes may turn on the outcome of such experimental drug trials inherently carries more risk than some other investments.”); *In re Vical Inc. Sec. Litig.*, No. 13-CV-2628, 2015 WL 1013827, at *8 (S.D. Cal. Mar. 9, 2015) (“[I]nvestments in experimental drugs are inherently speculative[,] [i]nvestors cannot, after failing in this risky endeavor, hedge their investment by initiating litigation attacking perfectly reasonable – if overly optimistic statements proved wrong only in hindsight.”).

The results of other Lucentis trials – to the extent relevant at all – were publicly available, as shown by Plaintiffs’ reliance on them herein. Indeed, all information now challenged by Plaintiffs was **publicly available** at the time Plaintiffs invested between the putative class period, April 8, 2014 and January 4, 2018 (Dkt. No. 15-2). (*See* fn. 1, *supra* & 33, *infra*.) Plaintiffs cannot now rely on such facts when they were widely available at the time of their investment and well before the Class Period. *See, e.g., In re Progress Energy, Inc.*, 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) (“[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed.”); *Deutsch v. Flannery*, 597 F. Supp. 917, 922 (S.D.N.Y. 1984) (observing fraud claim “cannot be based on failure to disclose the existence of . . . information [that] had already been disclosed”).

3. Ohr’s Statements Regarding Its Clinical Trials Cannot Support a Claim.

a. Many Challenged Statements Constitute Non-Actionable Optimism.

The myriad statements of Ohr that Plaintiffs challenge consist of certain optimistic statements regarding its ongoing clinical trials of Squalamine. Specifically, Plaintiffs continuously challenge Ohr’s statements which are mere inactionable statements of corporate optimism. (*See* Am. Compl. ¶ 10 (“touting the data as ‘truly remarkable’ and showing a ‘robust and rapid response’”); *see also id.* at ¶ 12 (describing IMPACT Trial visual acuity results as

“clinically meaningful” and showing “a clear efficacy signal”); *id.* at ¶ 68 (“robust” and “clinically meaningful” and showing a “dramatic effect in visual outcomes”).²⁴

As a matter of law, placing a positive gloss on data, mere general statements of optimism, and puffery are understood by reasonable investors as such and are not actionable. *See, e.g., Tongue*, 816 F.3d at 211-12 (finding that pharmaceutical company’s expression of “even exceptional optimism” about a drug’s approval was not misleading and, thus, not actionable); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557-59 (S.D.N.Y. 2004) (Preska, J.) (statements like “[w]e think Erbitux is real blockbuster potential” and “[Erbitux] has the potential to be one of the most exciting, if not the most exciting, oncology compound introduced over the next several years” were “non-actionable opinion, personal or corporate optimism and puffery”); *In re Sanofi*, 87 F. Supp. 3d at 538-39 (rejecting claims based on statements that trial results were “unprecedented,” “nothing short of stunning,” and “the best efficacy data that anybody has ever demonstrated”); *Shah v. GenVec, Inc.*, No. 12-0341, 2013 WL 5348133, at *15 (D. Md. Sep. 20, 2013) (approving “unjustifiably positive spin on the data available at the time of the first interim analysis by using terms like ‘encouraging’ and ‘bullish’” as “no more than puffery . . . and not actionable under § 10(b).”).²⁵ Thus, Defendants’ corporate optimism cannot be relied upon to establish Plaintiffs’ Section 10(b) claim.

²⁴ Specific to Plaintiffs’ nitpickings with regard to the use of the term “clinically meaningful,” Plaintiffs’ distinction is likewise not central for purposes of Section 10(b). *Lerner v. Nw. Biotherapeutics*, 273 F. Supp. 3d 573, 589 (D. Md. 2017) (“Section 10-b is not concerned with such subtle disagreements over adjectives and semantics.”); *see also In re Merrill Lynch Auction Rate Sec. Litig.*, 704 F. Supp. 2d 378, 392 (S.D.N.Y. 2010) (“semantic distinction [between ‘routinely’ and ‘systematically’] is not persuasive”).

²⁵ Further to management’s interpretation of the clinical trial data, “the law is clear that companies need not depict facts in a negative or pejorative light or draw negative inferences to have made adequate disclosures.” *Singh v. Schikan*, 106 F. Supp. 3d 439, 448 (S.D.N.Y. 2015) (rejecting allegation that defendants failed to highlight changes in enrollment criteria and describe potential negative impact of those changes where defendants detailed each study’s

b. The Remaining Challenged Statements Are Forward-Looking and Accompanied by Extensive and Meaningful Cautionary Language.

For biotechnology companies like Ohr, courts have routinely held that forward-looking statements include (1) predictions of approval of a new drug by regulatory agencies, (2) expectations about the successful completion of a clinical drug trial, (3) touting of possible drug effectiveness, (4) promotions of potential marketability of a new drug candidate, and (5) optimism regarding future profitability of a drug. *See In re Columbia Labs. Inc. Sec. Litig.*, 144 F. Supp. 2d 1362, 1368 (S.D. Fla. 2001); *In re Tech. Chems. Sec. Litig.*, No. 98-7334, 2001 WL 543769, at *8 (S.D. Fla. Mar. 20, 2001) (“a reasonable investor should take caution” from risk factors disclosing that the drug “requires governmental approval” in order to be marketable).

For example, in *City of Edinburgh Council*, Defendants described their drug bapineuzumab as a “potential ‘breakthrough’ drug” and “an example of a drug offering ‘opportunities for transformational growth of the company,’” at a Healthcare Conference. 754 F.3d at 173. The Court found these statements to be inactionable because they are vague, non-specific, and forward-looking. *Id.* Like Defendants’ statements in *City of Edinburgh Council*, Ohr’s forward-looking statements accompanied by meaningful cautionary language are inactionable under the PSLRA’s safe-harbor provision. 15 U.S.C. § 78u-5(c)(1)(A)(i).²⁶ These

design, allowing investors to compare information themselves); *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 631 (S.D.N.Y. 2008) (“[C]orporate officials need not present an overly gloomy or cautious picture so long as public statements are consistent with reasonably available data.”); *In re Sierra Wireless, Inc. Sec. Litig.*, 482 F. Supp. 2d 365, 367 (S.D.N.Y. 2007) (no requirement that corporate officers “adopt a crabbed, defeatist view of the company’s business prospects”).
²⁶ Ohr’s disclosures included thorough and frequent risk disclosures, making clear that the clinical trials might prove unsuccessful. *See, e.g.*, Ex. 3 at 7 (“The results of our clinical trials with respect to any drug candidate might not support our claims of safety or efficacy.”); Ohr Pharm., Inc.’s Form 10-K/A, Ex. 99.1 Press Release (Jan. 19, 2010), at 2 (“Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the future success of our scientific studies . . .”), annexed as Ex. 35 to Cassirer Affirm.; Ohr Pharm., Inc.’s Annual Report (Form 10-K) (Jan. 9, 2013), at 7, annexed as Ex. 36 to Cassirer Affirm.; Ohr Pharm., Inc.’s Form 8-K, Ex.

are precisely the type of forward-looking statements upon which Plaintiffs attempt to hinge Defendants' alleged liability. (*See* Am. Compl. at ¶ 74 (“On July 12, 2017, Kaiser predicted a 60% chance of success of the MAKO Trial.”); *id.* (“[O]n December 18, 2017, Kaiser ... upped his prediction to a 75 to 80% chance of success of the MAKO Trial.”).) The statements Plaintiffs rely on are not only covered by the risk disclosures therein but also are textbook examples of protected forward-looking statements.

4. Statements of Independent Third Parties Are Not Attributable to Ohr and Are Not Actionable.

The Complaint quotes several third-party promoter and analyst reports that were allegedly published during the Class Period to support a claim of fraud. (*Id.* at ¶¶ 43, 59-61.) To the extent Plaintiffs attempt to premise any claim on such third parties, their efforts are misplaced. Hiring a third-party stock promoter to publicize clinical trial results is not inappropriate by itself. *See United States v. Hall*, 48 F. Supp. 2d 386, 387 (S.D.N.Y. 1999) (“A company may lawfully seek to ‘manipulate’ the market by hiring legitimate stock promoters who disseminate information about the company to the public.”).²⁷

99.1 Press Release (Feb. 20, 2014), at 2 (“Shareholders and prospective investors are cautioned that no assurance of the efficacy of pharmaceutical products can be claimed or assured until final testing . . .”), annexed as Ex. 37 to Cassirer Affirm.; Ohr Pharm., Inc.’s Press Release (Mar. 27, 2015), at 2 (“Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the future success of our scientific studies . . .”), annexed as Ex. 38 to Cassirer Affirm.; Ohr Pharm., Inc.’s Quarterly Report (Form 10-Q) (Feb. 9, 2016), at 22, annexed as Ex. 39 to Cassirer Affirm.; Ohr Pharm., Inc.’s Annual Report (Form 10-K) (Dec. 15, 2017), at 1, annexed as Ex. 40 to Cassirer Affirm.

²⁷ Plaintiffs further suggest there is some impropriety and violation of 15 U.S.C. § 77q(b) in the failure of Vista Partners LLC (a third-party promoter) to make a prominent enough statement that it was paid by Ohr in its report. (*See* Am. Compl. ¶ 60.) Even if that were true (the disclosure was contained in the press release), the duty to disclose stock promoter payments does not fall on Ohr but, rather, falls on the party that receives the payments – here, Vista. *See In re Galectin Therapeutics, Inc. Sec. Litig.*, 843 F.3d 1257, 1272 (11th Cir. 2016) (noting “the duty to disclose payments for promotional articles is on the author who receives the payment”). Thus, the allegation cannot state any claim against Defendants.

Moreover, Plaintiffs do not allege a basis for attributing the analysts' statements to the Individual Defendants. "[T]he law is clear that a defendant may be held liable under Rule 10b-5 only if it 'made' the statement itself." *Cortina v. Anavex Life Scis. Corp.*, No. 15-CV-10162 (JMF), 2016 WL 7480415, at *4 (S.D.N.Y. Dec. 29, 2016); *see also Janus Capital Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011) (the maker of a statement is "the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it. Without control, a person or entity can merely suggest what to say, not 'make' a statement in its own right."). Thus, the statements of third-party analysts are not actionable. *See In re PDI Sec. Litig.*, No. 02-211(GEB), 2006 WL 3350461, at *6 (D.N.J. Nov. 16, 2006) (failed to allege "facts showing that a particular defendant both made the statement to the analyst and controlled the content of the analyst's report"); *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 403 (D.N.J. 2010) ("The complaint must rise or fall on allegations about defendant[s] conduct and not on wide-eyed citation to the gratuitous commentary of outsiders.").

In re Galectin Therapeutics, Inc. Securities Litigation is particularly instructive on this point. In interpreting the Supreme Court's decision in *Janus*, the Eleventh Circuit held:

While [plaintiff] has set forth allegations that the defendants worked in conjunction with stock promoters to promote [the issuer's] stock, particularly with respect to the timing of articles by the stock promoters and company press releases, [plaintiff] has not included sufficient allegations to support a finding that [the issuer] had 'ultimate authority' or 'control' over the stock promoters' statements. Even though [the issuer] paid for the stock promoters' articles, that is not sufficient to support a claim under Rule 10b-5(b). Payment for the promotional articles does not mean that [the issuer] is the maker of the statements in the articles.

843 F.3d at 1272 (citations omitted); *see also In re WRT Energy Sec. Litig.*, Nos. 96 Civ. 3610, 3611, 1997 WL 576023, at *10 (S.D.N.Y. Sept. 15, 1997), *vacated on other grounds by In re*

WRT Energy Sec. Litig., No. 02-7829, 2003 WL 22221341 (2d Cir. 2003) (dismissing Section 10(b) claim based on statements attributed to third-party analysts).²⁸

B. Plaintiffs Fail to Allege Facts Sufficient to Raise a Strong Inference of Scienter.

The Second Circuit has held that plaintiffs can meet the PSLRA’s stringent scienter requirement only by either alleging specific facts demonstrating (i) “strong circumstantial evidence of conscious misbehavior or recklessness,” or (ii) “that defendants had both motive and opportunity to commit fraud.” *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290-91 (2d Cir. 2006); *Stratte-McClure v. Stanley*, 776 F.3d 94, 106 (2d Cir. 2015). While Plaintiffs claim scienter has been established on both prongs (Am. Compl. ¶ 157), their own allegations prove them wrong.

1. Plaintiffs Do Not Adequately Plead Motive and Opportunity on the Part of the Individual Defendants.

a. The Individual Defendants Did Not Sell Any Stock and, Rather, Increased Their Holdings During the Putative Class Period.

To establish motive of Ohr’s directors and officers, Plaintiffs must allege that the Individual Defendants “benefitted in some concrete and personal way from the purported fraud.” *Novak v. Kasaks*, 216 F.3d 300, 307-08 (2d Cir. 2000). Plaintiffs’ half-hearted attempt to establish motive fails, as there was no pecuniary gain to any Individual Defendants through the sale of stock and any capital raising was consistent with the goal of all corporations – to profit.

Plaintiffs notably do not and cannot allege that any Individual Defendant profited by making any stock sales during the class period. Indeed, they bought stock and received

²⁸ Similarly, any news media report that picked up those promoter pieces cannot be a basis for Ohr’s liability. *See Zagami v. Cellceutix Corp.*, No. 15-CV-7194 (KPF), 2016 WL 3199531, at *6-7 (S.D.N.Y. June 8, 2016) (holding statements in internet article not attributable to the defendant because plaintiff failed to show that the defendant had “ultimate authority” over the publication of the article in question, despite defendant being directly quoted).

compensation in the form of stock during the relevant period.²⁹ And, the fact that the Individual Defendants retained their shares undermines any inference of scienter because “[t]he absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders’ expense, is inconsistent with an intent to defraud shareholders.” *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) (citation omitted); *see also Turner v. MagicJack VocalTec, Ltd.*, No. 13 Civ. 0448, 2014 WL 406917, at *11 (S.D.N.Y. Feb. 3, 2014) (lack of suspicious stock sales “rebut[s] an inference of scienter”); *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 289 (S.D.N.Y. 2006).³⁰ More significantly, the fact that the Individual Defendants did not sell any stock and even increased their stock holdings during the relevant period eviscerates any hint of pecuniary motive. *See In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d at 561 (finding increase in shareholdings “wholly inconsistent with fraudulent intent”); *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 383 (E.D.N.Y. 2003).

b. A Company’s Desire to Raise Capital Provides No Basis for Scienter.

Plaintiffs’ attempt to establish Ohr’s financial motive falls flat. Plaintiffs claim that – “[u]nlike most companies” – Ohr was attempting “to raise desperately needed capital to stave off bankruptcy.” (Am. Compl. ¶ 124.) But the desire to raise capital for continued operations is common to virtually all corporate directors and officers and cannot form the basis for a finding of scienter. *See, e.g., Tabak v. Canadian Solar, Inc.*, 549 F. App’x 24, 28 (2d Cir. 2013) (finding desire to raise capital insufficient to establish motive because it is a goal “possessed by virtually

²⁹ *See, e.g.*, Ohr Pharm., Inc.’s Ownership Document (Form 4) (Feb. 10, 2015), annexed as Ex. 41 to Cassirer Affirm.; Ohr Pharm., Inc.’s Ownership Document (Form 4) (Apr. 12, 2016), annexed as Ex. 42 to Cassirer Affirm.; Ohr Pharm., Inc.’s Ownership Document (Form 4) (Apr. 13, 2017), annexed as Ex. 43 to Cassirer Affirm.

³⁰ Plaintiffs have not alleged, and there is no evidence to indicate, that any insider sales or purchases have taken place in the present case. A copy of the Ohr Pharmaceutical, Inc. Insider Trading Activity report, downloaded from the NASDAQ website and annexed as Ex. 44 to Cassirer Affirm., confirms this point.

all corporate insiders”); *In re DRDGOLD Ltd. Sec. Litig.*, 472 F. Supp. 2d 562, 570 (S.D.N.Y. 2007) (raising capital cannot support an inference of scienter); *In re MELA Scis., Inc. Sec. Litig.*, 2012 WL 4466604, at *5 (“To the extent the [complaint] relies on MELA’s capital raised during the Class Period, the Court also finds this inadequate to support an allegation of intent to commit fraud.”); *Tamar v. Mind C.T.I., Ltd.*, 723 F. Supp. 2d 546, 555 (S.D.N.Y. 2010) (collecting cases). The *need* for capital and desire to avoid bankruptcy do not change the calculus and have been routinely rejected as insufficient to establish scienter by courts within the Second Circuit. *See In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 532 (S.D.N.Y. 2009) (holding motive to raise capital to “prevent [] negative ramifications” – even where they would “threaten the ‘survival’ of a company – is far too generalized (and generalizable)”); *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 216 (S.D.N.Y. 2008) (“Any corporation would be motivated to make a profit, to avoid bankruptcy, or to finance the successful launch of a promising product. . . . These allegations do not support an inference of scienter.”).

c. Maximization of Corporate Profits Is No Basis for Scienter.

Plaintiffs’ sole remaining allegation of motive is that, because Ohr’s “primary business” was the development of Squalamine and “Squalamine was the Company’s sole drug at the clinical trial stage and only hope for a commercialized product,” Defendants were motivated to exaggerate the drug’s success, and, thus, their knowledge can be presumed. (Am. Compl. ¶¶ 129-30.) These allegations likewise are not sufficient to support a finding of scienter. *See, e.g., Jackson v. Halyard Health, Inc.*, No. 16 Civ. 5093, 2018 WL 1621539, at *8 (S.D.N.Y. Mar. 30, 2018) (finding that Defendants’ desire “to take advantage of the Ebola pandemic scare” was insufficient to allege motive because the statement merely reflected corporate insiders’ common desire that the company appear profitable and maintain its stock price); *Fialkov v. Alcobra Ltd.*, No. 14 Civ. 09906, 2016 WL 1276455, at *7 (S.D.N.Y. Mar. 30, 2016) (complaint

fails to plead scienter where its only allegation supporting scienter is that the drug is the company's sole drug candidate).³¹

Because Plaintiffs have not alleged that the Individual Defendants "benefitted in some concrete and personal way from the purported fraud," but rather only alleged a desire common to corporate insiders – for their company to be successful and profitable – they have failed to establish scienter. *See In re Neurotrope, Inc. Sec. Litig.*, No. 17 Civ. 3718 (LGS), 2018 WL 2561024, at *8 (S.D.N.Y. June 4, 2018) (quoting *Novak*, 216 F.3d at 307-08).

2. Plaintiffs Do Not Adequately Plead Conscious Misbehavior or Recklessness.

The Complaint is devoid of any factual allegation that, if true, would show that Ohr engaged in conscious misconduct or recklessness. Where, as here, there is no motive, the "strength of the circumstantial allegations must be correspondingly greater." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001); *see also Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 579 (S.D.N.Y. 2016) ("[W]here plaintiffs do not sufficiently allege that defendants had a motive to defraud the public, they 'must produce a stronger inference of recklessness.'"). "The Second Circuit has stated that securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation. This recklessness is an extreme departure from the standards of ordinary care." *Abely*, 2013 WL 2399869, at *17 (quoting *Novak*, 216 F.3d at 308). When proceeding on a

³¹ Plaintiffs' allegations completely ignore the considerable tension in this District concerning the continued viability and scope of the "core operations" pleading doctrine after the passage of the PSLRA. *See In re ShengdaTech, Inc. Sec. Litig.*, No. 11 CIV. 1918, 2014 WL 3928606, at *9 (S.D.N.Y. Aug. 12, 2014) ("[G]eneral allegations regarding a defendant's involvement in the 'core operations' of a business cannot serve as an independent basis for scienter."); *Bd. of Tr. of City of Ft. Lauderdale Gen. Emp.'s Ret. Sys. v. Mechel OAO*, 811 F. Supp. 2d 853, 871 (S.D.N.Y. 2011). Thus, even if "core," this adds nothing to the scienter equation.

recklessness theory of scienter, a complaint must plausibly allege that defendants “*knew* facts or had access to information suggesting that their public statements were *not accurate*.” *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 194 (2d Cir. 2008) (emphasis added); *see also Express Scripts Holding. Co. Sec. Litig.*, 2018 WL 2324065, at *9.

As discussed above, Ohr management had good clinical and business reasons to purchase Squalamine and to proceed with further development. Further, Ohr publicly stated that the CATT Trial of Lucentis was the comparator relied upon, and Plaintiffs’ cherry-picking of those public statements reveals their deliberate effort to create an improper and inaccurate inference. Specifically, the Complaint cites Slakter “admit[ing]” in a December 22, 2016 conference call that “[w]hen [Ohr] first evaluated [its] phase 2 data, one of the first things [management] looked at was how closely our Lucentis monotherapy control arm performed compared to prior studies.” (Am. Compl. ¶ 119 (emphasis omitted).) Yet, Plaintiffs conveniently fail to mention that Defendant Slakter immediately thereafter continued:

As you recall the Lucentis PRN arm of the CATT trial, which was the large study comparing Lucentis to Avastin had a treatment regimen inclusion criteria almost identical to that that we used in our study. And we saw that the outcome in our Lucentis monotherapy arm were very similar to the visual acuity outcomes seen in the comparable arm in the CATT study at months nine. This provided us with support to the improvements that we were seeing with Squalamine combination therapy in Phase 2 were real and replicable.

(Ex. 34.) Plaintiffs’ speculation regarding other clinical trials – other trial results widely published in the scientific community, but demonstrably distinguishable – does not vitiate Defendants’ opinion that only the CATT Trial was an appropriate comparable, and, thus, weighs against a finding of scienter.

Mere allegations of knowledge of other clinical trial results cannot transform a difference of opinion in the significance of certain data into a claim recognized under the securities laws.

See, e.g., In re Vertex Pharm. Inc. Sec. Litig., 357 F. Supp. 2d 343, 354-55 (D. Mass. 2005) (“The existence of scientific disagreement . . . as to the potential viability of a drug in development, without more details about the substance of the debate, cannot provide the necessary strong showing of scienter.”). For example, in *Kelley v. Aerie Pharmaceuticals, Inc.*, No. 15-cv-3007, 2016 WL 3437603, at *9-10 (D.N.J. June 20, 2016), the court declined to second-guess the company’s optimistic expectations, which were ultimately found to be based on incorrect assumptions. Specifically, Aerie had conveyed to investors its expectations for the success of its development-stage drug in competition against two other drugs on the market, based upon comparing its Phase 2b trial results to prior medical studies of the other two competing drugs. 2016 WL 3437603, at *1. Aerie then conducted a Phase 3 trial to compare its drug to the second competing drug, but the trial failed to meet its expectations, and its stock price subsequently dropped significantly. *Id.* The plaintiffs filed suit days later, claiming Aerie ***should have been aware*** of the incorrect assumptions and that Aerie’s positive statements were misleading, but the court dismissed the complaint with prejudice for lack of scienter. *Id.* at 2. The same result is warranted here – the disagreement over what facts were significant to Lucentis studies as comparable do not support a finding of scienter.

Moreover, Plaintiffs’ simplistic approach to the “unsuccessfulness” of Genaera is not only inaccurate but also ignores that Ohr had reformulated³² the drug after acquiring it such that it was a wholly different application – *i.e.*, intravenous versus eye drops and monotherapy versus combination therapy. (*See* Ex. 19 (“As opposed to the approved current standard of care therapy, Squalamine does not require direct injection into the eye.”).) That the Individual Defendants had access to information showing the Squalamine trials were discontinued is not disputed, given

³² Plaintiffs pejoratively refer to the application as “repackaging.” (*See* Am. Compl. at ¶ 44.)

Genaera's press releases and disclosures related to those very trials. (*See* Am. Compl. ¶¶ 128-29.)³³ Additionally, the low price of Genaera when purchased out of the bankruptcy does not itself show that the drug was "only \$200,000" but, rather, undervalued. (*Id.* at ¶¶ 2, 41.) In fact, creditors in Genaera's bankruptcy filed a lawsuit claiming that it was fraudulent for the liquidating trustee to sell the drug out of the estate at the \$200,000 selling price, an alleged "unacceptable price." Complaint, *Schmidt v. Skolas*, Civil Action No. 2:12-cv-03265-BMS (E.D. Pa. June 8, 2012), ECF 1.

While Plaintiffs claim that the Individual Defendants had access to prior clinical trials and results and, thus, would have known the outcome of the studies (Am. Compl. ¶¶ 118-23), they ignore that the only clinical trials deemed remotely relevant by Ohr were the CATT trials, which had some similar parameters and data points allowing for appropriate comparison. (*See* pp. 16, 26, *supra*.) Like the Court's finding in *Express Scripts Holding. Co.*, and as discussed herein, Plaintiffs have not adequately pled any allegation to establish that Defendants' opinions and interpretations were not honestly believed or that Defendants "**knew** their public statements about [the data at issue] **were incorrect**." 2018 WL 2324065, at *9 (emphasis added). Plaintiffs' allegations of what Defendants should know does not negate Defendants' ability to make informed judgments regarding the clinical trial data. "The most plausible inference" to draw from Plaintiffs' allegations and Defendants' corresponding disclosures is "that [D]efendants honestly believed their descriptions of the data." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 546. Plaintiffs' claim breaks down as any inference of scienter drawn from Plaintiffs' allegations is

³³ This is made clear by Plaintiffs' ability to even draft their Complaint. This information has been publicly available since the announcement was first made in 2007. And Ohr repeatedly disclosed that its purchase of Squalamine was traceable to Genaera. *See* Ex. 2 ("We acquired OHR/AVR118 in a secured party sale and Squalamine from the Genaera Liquidating Trust as part of the Company's previous strategy to create a rollout of undervalued biotechnology companies and assets.").

not “plausible or reasonable,” let alone “cogent and at least as compelling as any opposing inference.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

Consequently, Plaintiffs’ claim should be dismissed for want of scienter.

3. Plaintiffs Have Not Adequately Alleged Corporate Scienter.

“When the defendant is a corporate entity, . . . the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter. In most cases, the most straightforward way to raise such an inference for a corporate defendant will be to plead it for an individual defendant.” *Teamsters Local 445 Freight Div. Pension Fund*, 531 F.3d at 195. Plaintiffs do not allege scienter against any Individual Defendant whose intent could be imputed to the Company and, thus, Plaintiffs’ claim against Ohr – premised solely on this basis (Am. Compl. ¶ 101) – also fails.

C. Plaintiffs’ Claim Should Be Dismissed for Failure to Plead Loss Causation.

Plaintiffs’ failure to allege loss causation provides an independent ground to dismiss the Complaint. Loss causation is “the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.” *Lentell*, 396 F.3d at 172; 15 U.S.C. § 78u-4(b)(4) (PSLRA requires plaintiffs to plead “that the act or omission of the defendant alleged . . . caused the loss for which the plaintiff seeks to recover damages”). “[P]laintiffs must show ‘a sufficient connection between [the fraudulent conduct] and the losses suffered.’” *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 510 (2d Cir. 2010). Plaintiffs have not done so here.

1. Plaintiffs Allege No “Corrective Disclosures.”

This theory of loss causation requires that “a corrective disclosure informed the market of the fraud, and the market reacted negatively.” *In re Francesca’s Holdings Corp. Sec. Litig.*, Nos. 13-cv-6882 (RJS), 13-cv-7804 (RJS), 2015 WL 1600464, at *18 (S.D.N.Y. Mar. 31, 2015). According to Plaintiffs, the announcement that Squalamine failed in the MAKO Trial – the

precise risk about which Ohr repeatedly warned investors³⁴ – caused the stock drop. (Am. Compl. ¶¶ 16, 142). Plaintiffs do not explain any connection between the misstatements alleged and the January 5, 2018 announcement regarding the MAKO Trial. (*See id.*) But it did not reveal any new facts previously withheld or expose any prior statement as misleading. Rather, it explained that the MAKO Trial – a new independent study conducted after the IMPACT trial – did not achieve its primary efficacy endpoint of mean visual acuity gain at nine months.³⁵

Nothing in the announcement permits an inference that Defendants knew any of those facts in advance. In fact, due to the study being masked, the defendants had no knowledge of the topline data results until just prior to the announcement on January 5, 2018. By definition, a corrective disclosure must reveal “to the market that a defendant’s prior statements were not entirely true or accurate.” *Police & Fire Ret. Sys. of City of Detroit v. SafeNet, Inc.*, 645 F. Supp. 2d 210, 228 (S.D.N.Y. 2009). Without showing how Ohr’s January 5, 2018 press release announcing the final results of the Phase III trial constituted a corrective disclosure – *i.e.*, revealed that previous statements or omissions were false – the Complaint, at best, advances a narrative in which Ohr’s stock price dropped on the disappointing news that a promising treatment for wet-AMD did not succeed in its next clinical trial.

This is a common occurrence for clinical stage biotechnology companies, and it does not establish loss causation. *See In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 384 (E.D.N.Y. 2013) (“[L]oss causation is not adequately pled simply by allegations of a drop in stock price following an announcement of bad news if the news did not disclose the fraud.”) (citing *Leykin v. AT&T*, 423 F. Supp. 2d 229, 245 (S.D.N.Y. 2006)); *see also Bonanno v. Cellular Biomedicine Grp.*,

³⁴ *See supra*, fn. 26.

³⁵ *See* Ohr Pharm., Inc.’s Form 8-K, Ex. 99.1 Press Release (Jan. 5, 2018), annexed as Ex. 45 to Cassirer Affirm.

Inc., No. 15-CV-01795-WHO, 2016 WL 2937483, at *6 (N.D. Cal. May 20, 2016) (“Loss causation is not adequately pled unless a plaintiff alleges that the market learned of and reacted to the practices the plaintiff contends are fraudulent, as opposed to merely reports of the defendant’s [negative results] generally.”) (citations omitted).

2. Plaintiffs Identify No “Materialization of a Concealed Risk

For an event to be the “materialization of a foreseeable risk concealed,” it must “reveal new information previously concealed and fall within the ‘zone of risk’ concealed so that the events were foreseeable consequences of the fraud.” *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 558 (S.D.N.Y. 2011), *aff’d sub nom.*, 838 F3d 223 (2d Cir. 2016). Thus, the materialization of risk theory requires that “the risk concealed from investors materialized and caused a foreseeable loss.” *In re Francesca’s Holding Corp.*, 2015 WL 1600464, at *18, 20.

All that “materialized” on January 5, 2018 were the risks that Defendants disclosed all along – that the MAKO Trial may fail to prove the efficacy of Squalamine. *See supra*, fn. 26. This cannot form the basis of a Section 10(b) claim. *In re Francesca’s Holding Corp.*, 2015 WL 1600464, at *21 (plaintiffs “must do more than simply point to . . . ‘bad news’ to plead loss causation”). Consequently, the Complaint should be dismissed.

POINT II.

PLAINTIFFS’ SECURITIES ACT CLAIMS GO BACK TO 2009 AND ARE BARRED BY THE STATUTE OF LIMITATIONS

Any claims arising under Section 10(b) or Section 20(a) must be filed no later than “the earlier of ‘(1) two years after the discovery of the facts constituting the violation; or (2) 5 years after such violation.’” *In re GlaxoSmithKline PLC Sec. Litig.*, No. 05 Civ. 3751 (LAP), 2006 WL 2871968, at *7 (S.D.N.Y. Oct. 6, 2006) (Preska, J.). The limitations period begins “when the plaintiff ‘obtains actual knowledge of the facts giving rise to the action or notice of the facts,

which in the exercise of reasonable diligence, would have led to actual knowledge.” *Shah v. Meeker*, 435 F.3d 244, 249 (2d Cir. 2006), *abrogated on narrower grounds by Merck & Co. v. Reynolds*, 559 U.S. 633 (2010). A duty of inquiry arises when “the circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded, circumstances otherwise known as ‘storm warnings.’” *GVA Mkt. Neutral Master Ltd. v. Veras Capital Partners Offshore Fund, Ltd.*, 580 F. Supp. 2d 321, 327 (S.D.N.Y. 2008) (citations omitted).

“[W]hether the securities fraud claim of a plaintiff who receives storm warnings is time barred turns on *when*, after obtaining inquiry notice, the plaintiff in the exercise of reasonable diligence, should have discovered the facts underlying the [defendant’s] alleged fraud.” *Meeker*, 435 F.3d at 249 (emphasis added). “Storm warnings” sufficient to provide investors with “inquiry notice” may include “any publicly available financial, legal, or other information, including news articles or the filings of other lawsuits alleging fraud against the defendants.” *GVA Mkt. Neutral Master Ltd.*, 580 F. Supp. 2d at 328; *see also LC Capital Partners, LP v. Frontier Ins. Grp., Inc.*, 318 F.3d 148, 155 (2d Cir. 2003) (affirming dismissal where single press article and lawsuit triggered inquiry notice); *Menowitz v. Brown*, 991 F.2d 36, 42 (2d Cir. 1993) (holding SEC filing provided investors with constructive notice and triggered limitations period).

Dismissal is appropriate “when the facts from which knowledge may be imputed are clear from the pleadings and the public disclosures themselves. ‘Plaintiffs need not be able to learn the precise details of the fraud, but they must be capable of perceiving the general fraudulent scheme based on the information available to them.’” *In re Ultrafem Inc. Sec. Litig.*, 91 F. Supp. 2d 678, 692 (S.D.N.Y. 2000) (Preska, J.) (citation omitted). In *Ultrafem*, this Court found that a Bloomberg News article put plaintiffs on inquiry notice of claims relating to the nondisclosure of failures of a device. *Id.* The article discussed prior devices, their failures, and

the fact that such failures were not mentioned in the defendants' Prospectus and, thus, was sufficient to time-bar claims made more than a year after its publication. *Id.* Here, the action was not filed until February 14, 2018. Facts sufficient to establish the alleged fraud were publicly available far before February 14, 2016, the latest date of accrual for the statute of limitations. By March 2015, a reasonably diligent investor not only would have begun an investigation but also would have discovered the facts underlying Plaintiffs' baseless allegations.

First, Plaintiffs' Section 10(b) claim is based in part on the allegations that Ohr was aware that Squalamine was ineffective when it purchased it from Genaera's bankruptcy in 2009 and "failed to mention . . . that Genaera itself had determined that the efficacy results from [Genaera's] trials were weak and did not justify further testing of Squalamine." (Am. Compl. ¶ 6.) Second, the Complaint alleges Ohr "had possession of or access to information showing that the Squalamine trials conducted by Genaera were not successful" because Ohr's Glen Stoller and Thomas Ciulla³⁶ worked as investigators on Genaera's Phase III trials and Ohr had acquired all previous clinical data upon purchasing Squalamine in Genaera's bankruptcy. (*Id.* at ¶¶ 53, 116.) But Plaintiffs' attempt to couch Ohr's knowledge of the failed Genaera trials as information gained in secret through inside knowledge fails. (*See id.* at ¶ 41.) Regardless of whether this is or is not the basis for Ohr's awareness, the information detailing Genaera's various Squalamine clinical trials were widely publicly available as early as 2006.³⁷ In fact, a July 2014 Seeking Alpha article directly questioned the connection of Squalamine to Genaera and noted its sale for "less than \$100,000," claiming the drug was "discarded as unviable."³⁸

³⁶ As noted above, Ciulla believed Squalamine should be tested for efficacy in topical delivery.

³⁷ *See id.* at ¶¶ 38-40; *see, e.g.*, Genaera Corp.'s Form 10-K (Mar. 7, 2006), annexed as Ex. 46 to Cassirer Affirm.

³⁸ Richard Pearson, "The Ugly Truth Behind Ohr Pharma," SEEKING ALPHA (July 1, 2014) (noting "information gleaned from recent Phase 2 trials has been known for more than 10 years")

Like the news article published before the complaint in *Ultrafem*, the Seeking Alpha article and related disclosures put Plaintiffs on inquiry notice of their claims against Ohr well before their complaint was filed and after the statute of limitations had run.

Further, in March/April 2015, after a 69% stock drop on disappointing clinical trial results, the law firms of Levi & Korsinsky and The Rosen Law Firm – plaintiffs’ class action lawyers – published class action notices soliciting Ohr shareholders to form a class action suit against Ohr for the same or similar allegations as pleaded in this action.³⁹ Prior public notices seeking plaintiffs to join a class action suit in 2015 based on strikingly similar circumstances that have now been pleaded in the Complaint are further evidence that a reasonably diligent plaintiff should have discovered facts constituting a violation no later than 2015.

In sum, Plaintiffs’ allegations are largely based on public data that was available more than two years before Plaintiffs asserted their Section 10(b) claims in this action on February 14, 2018. Plaintiffs’ complaints make clear that a reasonably diligent plaintiff would discover the facts constituting an alleged violation – Ohr’s awareness of Squalamine’s prior ineffectiveness and/or historical Lucentis trial results, even assuming their relevance – well before February 14, 2016. Though the statute of limitations cannot accrue until the purchase or sale of the security, Plaintiffs should have discovered this information before ever purchasing stock. The history of such an experimental drug is something a reasonable investor – indeed, even a non-sophisticated investor – would uncover given its widespread publication.

and “the recent surge in the stock has simply been the result of a stock promotion provided and paid for by Ohr management”), annexed as Ex. 47 to Cassirer Affirm.

³⁹ Rosen Law Firm Class Action Notice (Mar. 27, 2015), annexed as Ex. 48 to Cassirer Affirm.; Levi & Korsinsky, LLP Investor Alert (Mar. 27, 2015), annexed as Ex. 49 to Cassirer Affirm.

POINT III.

**THE COMPLAINT FAILS TO STATE A CLAIM AGAINST THE INDIVIDUAL
DEFENDANTS PURSUANT TO SECTION 20(A) OF THE EXCHANGE ACT**

To avoid dismissal of a Section 20(a) claim, Plaintiffs must plead (1) a primary violation by the controlled person, (2) control of the primary violator by the controlling person, and (3) that the controlling person was a culpable participant in the alleged fraud in some meaningful sense. *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 170 (2d Cir. 2000). Plaintiffs fail to plead a primary violation and, thus, the Section 20(a) claim also must be dismissed. *See Pehlivanian*, 2017 WL 1192888, at *6-8; *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 139 (2d Cir. 2011).

CONCLUSION

For the reasons stated herein, Defendants respectfully request that this Court dismiss the Amended Complaint in its entirety with prejudice.

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Respectfully submitted,

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